



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Doddabele L. Madhavi )  
Serial No. 10/735,335 )  
Filed: December 12, 2003 )  
For: Bioavailable Carotenoid-Cyclodextrin )  
Formulations For Soft-Gels and Other )  
Encapsulation Systems )

COMMISSIONER OF PATENTS AND TRADEMARKS  
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is filed in conformity with 37 C.F.R. §§1.56 and 1.97. Accordingly, copies of the art cited herein are provided:

<u>U.S. Pat. No.</u>	<u>Date</u>	<u>Name</u>
5,384,186	01-24-1995	Trinh, et al.

Publications

SKALKO-BASNET, et al., "Liposomes Containing Drug and Cyclodextrin Prepared by the One-Step Spray-Drying Method", Drug Dev Ind Pharm. 2000 Dec;26(12):1279-84.

YU, et al., "Effect of camphor/cyclodextrin complexation on the stability of O/W/O multiple emulsions", Int J Pharm 2003 Aug 11;261(1-2):1-8.

VALERO, et al., "Ternary naproxen: beta-cyclodextrin:polyethylene glycol complex formation", Int J Pharm 2003 Oct 20; 265(1-2):141-9.

VEIGA, et al., "Influence of surfactants (present in the dissolution media) on the release behaviour of tolbutamide from its inclusion complex with beta-cyclodextrin", Eur J. Pharm Sci. 2000 Jan;9(3):291-9.

TONNESEN, et al., "Studies of curcumin and curcuminoids, XXVII. Cyclodextrin complexation: solubility, chemical and photochemical stability", Int J Pharm. 2002 Sep 5;244(1-2):127-35.

MURA, et al., "Effects of the host cavity size and the preparation method on the physicochemical properties of ibuprofen-cyclodextrin systems", Drug Dev Ind Pharm. 1999 Mar;25(3):279-87.

ALEXANDER, et al., "Chiral discrimination in cyclodextrin complexes of amino acid derivatives: beta-cyclodextrin/N-acetyl-L-phenylalanine and N-acetyl-D-

phenylalanine complex", Proc Natl Acad Sci USA. 2002 Apr 16;99 (8) :5115-20. Epub 2002 Apr 09.

VAKILY, et al., "Inclusion complexation of heptakis (2, 6-di-O-ethyl)-beta-cyclodextrin with tiaprofenic acid: pharmacokinetic consequences of a pH-dependent release and sterospecific dissolution", J Pharm Sci. 1995 Aug;84 (8) :1014-9.

MURA, et al., "Influence of the Preparation Method on the Physicochemical Properties of Binary Systems of Econazole with Cyclodextrins", Int Journ of Pharm 193 (1999) 85-95

AHSAN, et al., "Mutual Inhibition of the Insulin Absorption-Enhancing Properties of Dodecylmaltoside and Dimethyl-B-Cyclodextrin Following Nasal Administration", Pharm Res 2001 May;18 (5) : 608-14.

LOCKWOOD, et al., "Improved Aqueous Solubility of Crystalline Astaxanthin (3,3'-dihydroxy-6,6'-B-carotene - 4,4"-dione) by Captisol (Sulfobutyl Ether B-Cyclodextrin)", Jour of Pharm Sci, Vol 92, 922-926 (2003).

SPIRICHEV, et al., "[Study of bioavailability of different forms of synthetic beta-carotene in volunteers]", Vop Pitan. 1996(6) :22-6. Article in Russian.

MIYAKE, et al., "Improvement of solubility and oral bioavailability of rutin by complexation with 2-hydroxypropyl-beta-cyclodextrin", Pharm Dev Technol 2000;5(3) :399-407.

### **REMARKS**

It respectfully is submitted that none of the foregoing art, alone or in combination, shows or proposes the present invention. Accordingly, favorable action on the application respectfully is requested.

Respectfully submitted,

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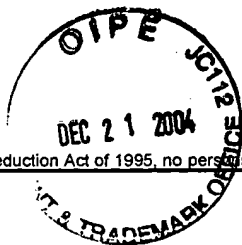
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Attorney Docket No.: BIO 2-016

  
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**Complete if Known**

Application Number	10/735,335
Filing Date	December 12, 2003
First Named Inventor	Doddabele L. Madhavi
Art Unit	1633
Examiner Name	Matthew L. Fedowitz
Attorney Docket Number	BIO 2-016

Sheet 2 of 3

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	SKALKO-BASNET, et al., "Influence of Surfactants (Present in the Dissolution Media) on the Release Behaviour of Tolbutamide from its Inclusion Complex with B-Cyclodextrin", Eu	
	2.	YU, et al., "Effect of camphor/cyclodextrin complexation on the stability of O/W/O multiple emulsions", Int J Pharm 2003 Aug 11;261(1-2):1-8.	
	3.	VALERO, et al., "Ternary naproxen: beta-cyclodextrin:polyethylene glycol complex formation", Int J Pharm 2003 Oct 20; 265(1-2):141-9.	
	4.	VEIGA, et al., "Influence of surfactants (present in the dissolution media) on the release behaviour of tolbutamide from its inclusion complex with beta-cyclodextrin", Eur J.	
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	6.	MURA, et al., "Effects of the host cavity size and the preparation method on the physicochemical properties of ibuprofen-cyclodextrin systems", Drug Dev Ind Pharm. 1999 Mar;25(	
	7.	ALEXANDER, et al., "Chiral discrimination in cyclodextrin complexes of amino acid derivatives: beta-cyclodextrin/N-acetyl-L-phenylalanine and N-acetyl-D-phenylalanine complex	
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	<b>Examiner Name</b>	Matthew L. Fedowitz
<b>Attorney Docket Number</b>		BIO 2-016

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